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(71) Applicant: MERCURY DIAGNOSTICS, INC. [US/US]; 4742 Scotts Valley Road, Scotts Valley, CA 95066 (US).

(72) Inventors: DOUGLAS, Joel, S.; 2048 Calabazas Boulevard, Santa Clara, CA 95051 (US). DREXLER, Andrew, M.; 12580 La Cresta Drive, Los Altos Hills, CA 94022 (US). RANEY, Charles, C.; 366 Collado Drive, Scotts Valley, CA 95066 (US). LEUNG, Edward, C.; 10383 Tonita Way, Cupertino, CA 95014 (US). YEE, Edison, F.; 359 San Luis Avenue, Los Altos, CA 94024 (US).

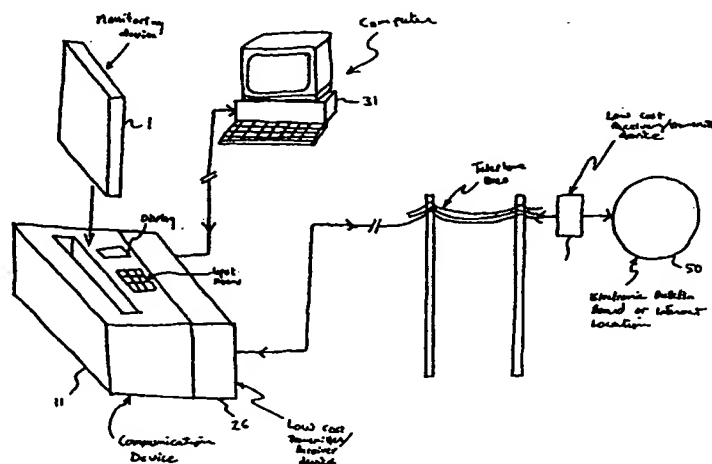
(74) Agents: DILLAHUNTY, T., Gene et al.; Burns, Doane, Swecker & Mathis, L.L.P., P.O. Box 1404, Alexandria, VA 22313-1404 (US).

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(54) Title: ANALYTE CONCENTRATION INFORMATION COLLECTION AND COMMUNICATION S YSTEM



(57) Abstract

A monitoring system which collects patient physiological data is designed specifically for communication with a communication module which facilitates data transfer from the monitoring system to a remote site. The communication module has data input mechanisms to facilitate setting parameters of the monitoring system and/or the communication module. The communication module is provided with a modem member which is used to communicate with the remote site and an optional data exchange module which is designed to communicate the same information with a local computer system. The remote site may be a bulletin board system or internet site where the monitoring information can be stored by the patient using the monitoring system by patient identification or name and include monitoring readings, time and date stamp, conditions such as meal times, exercise times and therapy amounts and their associated date and time.

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ANALYTE CONCENTRATION INFORMATION COLLECTION AND COMMUNICATION SYSTEM

5

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

10 The invention relates to the collection and communication of analyte concentration information, and more particularly, to a system for gathering and communicating such data for analysis and treatment.

DESCRIPTION OF RELATED ART

15 Numerous simple test devices have been developed to test for presence and quantity of analytes in aqueous samples, particularly whole blood. The patent and technical literature of the last thirty years is replete with inventions which utilize a dry chemistry reagent system or electrochemical methods to test for analytes in bodily fluids. These systems have been designed so that they can capture various pieces of
20 data such as time of day, date, calorie intake, exercise time and associated glucose readings.

 A large government-sponsored study (the DCCT) demonstrated conclusively that careful control of blood glucose levels can significantly reduce the incidence of serious complications of diabetes such as vision loss and kidney malfunction. Most
25 diabetics must test themselves periodically in order to make appropriate adjustments to their diet or medication. Thus, it is especially important for diabetics to have a simple and accurate means to capture their blood glucose readings and provide them to their health care provider for analysis of long-term control.

30

United States Patent 5,007,429 to Treatch *et al.* describes a user interface for direct programming of operating parameters for patient testing of blood pressure and downloading the data to an office control unit.

United States 5,019,974 to Beckers describes a diabetes management system and
5 apparatus for efficient medical control for diabetes comprising a recorder, interface module, and master computer which can develop programs of therapy which can be downloaded to the recorder to remind the patient of pending therapy actions.

SUMMARY OF THE INVENTION

10 The invention overcomes the shortcomings of the prior art by providing a monitoring system designed specifically for communication with a communication module which facilitates data transfer with a remote site. The communication module has data input mechanisms to facilitate setting parameters of the monitoring system. The communication module more specifically has a modem member which is used to
15 communicate with the remote site and an optional data exchange module which is designed to communicate the same information with a local computer system. The remote site is preferably a bulletin board system or internet site where the monitoring information can be stored by the patient using the monitoring system by patient identification or name and include monitoring readings, time and date stamp, conditions
20 such as meal times, exercise times and therapy amounts and their associated date and time.

The communication module can comprise the data transfer mechanisms described above and may also contain data entry devices for inputting information such as time and date which can then be downloaded to the monitoring system to reset these
25 parameters. Additional features which can be included in the communication module include function and data input keys to input other disease state information and a display for viewing this manually entered data.

The system may also be adapted to download from the remote site or a local computer time and date information to permit the communication module to
30 automatically set or change the time and date system in the communication module

FIG. 4 is a schematic representation of the communication module in communication with a local computer in accordance with the invention;

FIG. 5 is a schematic representation of a system in accordance with the invention in which a voice recognition system is employed;

5 FIG. 6 is a schematic representation of a communication module in connection with a monitoring instrument in accordance with the invention;

FIG. 7 is a schematic representation of the communication module in connection with the monitoring instrument and a remote location in accordance with the invention;

10 FIG. 8 is a schematic representation of the communication module in connection with the monitoring instrument and a remote location in accordance with a second embodiment of the invention.

DESCRIPTION OF THE INVENTION

This invention provides physiological information collection and communication
15 for patient disease management through the utilization of a system comprising a monitoring instrument, communication device and remote data collection site, thereby providing many benefits to patients controlling their disease state with intensive therapy. One such a task is the tight control of diabetes where the patient derives substantial benefit therefrom. Of course it is contemplated that the device can be used
20 for testing for any analyte and it is not intended that the scope be limited to patient physiological data.

As seen in FIG. 3, an arrangement in accordance with the invention comprises a monitoring instrument 1 (FIG. 2) which can be used to gather physiological information during a collection mode. This physiological information may be the presence or
25 concentration of an analyte of the patient, such as blood glucose level for diabetes control and treatment, or an analyte of urine or of interstitial fluid. The gathered information may be converted into information data and stored for uploading, via a communication module 11 during an interface mode, at a later time. The monitoring instrument 1 comprises a detection/analysis system 2 which is used to gather patient
30 physiological data, such as blood glucose level, in any manner familiar to those skilled

in the art, and may include optical testing of a sample on a sample strip impregnated with a suitable reagent. In such an optical arrangement, the analyte in the sample reacts with the reagent, with the reaction producing a physically detectable change which may entail an increase or decrease of a certain color component readily detectable via, for instance, electro-optical observation and measurement. LEDs and photodetectors may be used for this purpose in a well known manner. Alternatively, conductive probes may be used to measure the changed electrical conductivity between points on the sample strip due to the progression of the reaction of the analyte with the reagent.

As shown in FIG. 2, the monitoring instrument 1 is also equipped with a memory module 4 which is used for storing various information, including the gathered physiological information and instructions for proper operation of the monitoring instrument 1. Control of the monitoring instrument 1 is effected using a microprocessor 3 operating in conjunction with a system clock 5. A rechargeable battery pack or other power source (not shown) may be provided to furnish the necessary power for operation.

In practice the patient may use the monitoring instrument 1 for some number of times to effect the collection of the physiological information. Subsequently, the patient connects the monitoring instrument 1 with a communication module 11 (FIG. 1) which establishes communication with the monitoring instrument 1 and reads the data stored in the memory of the monitoring instrument 1 during an interface mode. The interface mode is illustrated schematically in FIG. 6. The connection between the monitoring instrument 1 and the communication module 11 can be via cable, using e.g., a connection port 12, or it may be more direct, through physical mating of the two devices such that associated leads or pins contact each other to establish an electrical connection. Other communication schemes between the two devices are also contemplated and may include optical or ultrasonic ("remote control") type connections. The interface mode may also entail a charging session concurrent with the other interface activities, such as the memory download, and would comprise the use of a battery charging system (not shown) provided in or with the communication module 11 which engages the battery pack of the monitoring instrument 1 for recharging thereof.

As shown in FIGS. 1 and 4, the communication module 11 comprises a microprocessor 13 which controls the operation of the various components, including a display 14, data entry means 15, transfer mode selection device 21, random access memory 18, read only memory 18, serial or parallel local computer system communication system 20 and modem system 16. The communication module 11 is provided with a telephone system connection means 17 and local system connection means 22 which effect the linking functions for connection and communication with remote locations such as sites 50 (FIG. 7) which may be an internet location or an electronic bulletin board, or a local computer 31 connected via, e.g., a cable link 32 (FIG. 4).

The patient can use display 14 of the communication module 11 to review the data, or the communication module can be permitted to automatically contact the remote site 50 or local computer 31 and transfer the data to a data storage system (not shown) provided at the remote location. Such automatic transfer would require little or no involvement by the patient—the communication module 11 senses the presence or connection of the monitoring instrument 1 thereto and automatically commences information transfer to the remote site 50 and/or local computer 31. The information exchange between the communication module 11 and the remote locations may be bidirectional, such that the data storage system at the remote location is capable of transferring correct time and date and other information to the communication module 11, which can use it to reset its clock and/or the clock in the monitoring device 1.

Two types of communication are selectable by the patient through the data entry means 15, which may be a control pad or key pad or other input mechanism. The patient, after connecting the monitoring instrument 1 with the communication module 11, can select either a local transfer (to, e.g., the local computer 31 as shown in FIG. 4) or a remote transfer of data to a data storage system disposed at the remote site 50 such as the internet site or electronic bulletin board (FIG. 7). As discussed above, it is contemplated that the transfer itself can be automatically activated upon completion of the connection process of the monitoring instrument 1 and the communication module 11, e.g., in a situation where these two components matingly engage each other,

no more than eight discrete tones in this case, all transmittable information used in the operation in accordance with the invention can be encoded, and simple transmit and receive devices can be utilized in lieu of conventional modems such as modem 16.

Such devices are well known and can be obtained at a fraction of the cost of

5 conventional modems.

Alternatively, the device 26 can use Morse code to transmit similar information by using either analog pulses or frequency tones as the dots, dashes and spaces used in Morse code. Again a reduced set of discrete signals is used, rather than the complex analog modem alternative, and an attendant cost saving is realized. The analog pulses
10 could be either dial pulse or frequency pulses. The system could also be configured with a DTMF tone to represent either the dot or dash. If 697 Hz was a dot, 852 Hz a dash, 1633 Hz a space then the code could be sent with a series of tones of specific duration. The use of a dial pulse could also be substituted and this in accomplished through a momentary interruption in the direct current in the loop of the calling system.
15 Accordingly, the system can be limited to a set of three distinct characters used to encode the transmitted information, the characters comprising the dot, dash, and space as encoded in any desired manner, for example DTMF.

Digit	Morse Code	DTMF
1	.----	697 Hz, 825 Hz, 852 Hz, 852 Hz, 852 Hz
2	..---	697 Hz, 697 Hz, 852 Hz, 852 Hz, 852 Hz
3-	697 Hz, 697 Hz, 697 Hz, 852 Hz, 852 Hz
4	697 Hz, 697 Hz, 697 Hz, 697 Hz, 852 Hz
5	697 Hz, 697 Hz, 697 Hz, 697 Hz, 697 Hz
6	---.	852 Hz, 852 Hz, 852 Hz, 852 Hz, 697 Hz
7	---..	852 Hz, 852 Hz, 852 Hz, 697 Hz, 697 Hz
8	---...	852 Hz, 852 Hz, 697 Hz, 697 Hz, 697 Hz
9	-....	852 Hz, 697 Hz, 697 Hz, 697 Hz, 697 Hz
0	-----	825 Hz, 825 Hz, 852 Hz, 852 Hz, 852 Hz

Similar systems could be arranged with Baudot or ASCII systems. The idea could be modified so that the number of dial pulses indicated the value to be sent separated by predetermined length of space as the delimiter between digits. An alternate method would be to assign a dot or dash value to a specific dial pulse signal such as 1 dial pulse is a dot, 2 dial pulse is a dash and using two predetermine length of time between dial pulses as delimiters between dots & dashes and between digits. This would permit the system to send data at high speeds using the momentary interruption of the direct current of the phone system. If the data was all decimal information then each digit is represented by 5 dots or dashes and the separation indicator BT is represented by _..._, end of transmission is represented by _._. and Wait is represented by _.... . These could all be used as delimiters to achieve logical breaks between data and identify CRC data. The ASCII code requires a minimum of seven separate indicators to be sent for each digit but this could be truncated to 4 if only digits were being transmitted. The delimiters available using a 4 digit code could be colon, semi colon, less than, greater than, equal to, and question mark. The Baudot code requires 5 digits to be transmitted.

A typical session could be formed with the following sequence of steps. The communication device 26 dials the appropriate telephone address (number) and initiates the session. A CRC which indicated the check sum of the data would be sent followed by a delimiter. The data would then be transferred following a specific format of the data. Any of the transmission systems discussed (DTMF or digital pulse coupled with either Mores Code, Baudot, or ASCII for example) could be used to send the data. For a blood glucose monitoring device, one possible format is: blood glucose level-3 digits; month-2 digits; day-2 digits; hour-2 digits; minute-1 digit, in 6 minute segments. An example is 1201201091 which would equal 120 mg/dl on December 1 at 09:10. Various data could be compressed into this scheme and various applications could then have a reasonably priced data collection system. The complete session could be as follows:

	Sending device	Answering device
15	Dial the telephone address	
		Answer the call
		Send a start indicator/delimiter "#"
	Send the CRC followed by a delimiter #	
20	Send the Social Security # and patient ID	
	Send the blood glucose information 1201201091	
	Send the end of transmission delimiter #	
		Calculate the CRC and check
25		

This methodology reduces the cost of data collection in the following ways. The cost of the communication equipment is reduced due to the elimination of the more robust modem technology and its associated Digital Single Process (DSP) electronics at both ends of the transaction. A low cost device is designed to receive specific DTMF tones or dial pulses and feed them to a simple microprocessor for decoding the signal.

The use of a digital pulse system is such that simple transistor switching systems can be used to receive the information. Additionally, by being able to send compact and specific information the connection time required to send the information is reduced, which reduces the cost of the transmission. Currently slow speed 300 to 9600 baud full
5 function modems have a cost which starts at \$20.00 for components alone. A dial pulse system of the current invention has a cost of \$30.00. It is within the purview of the invention to use a system based on a 4 to 8 bit Microcontroller such as the Intel 8051 using FSK with data compression to increase the speed of the transfer. Various data compression techniques could be utilized to reduce the amount of data transferred in a
10 known manner.

The invention does not require the patient to have any knowledge of computerized systems to complete the download and transfer features, making the data collection available to a large number of patients who do not have or use a computer system. The data is automatically exchanged in this case via modem to the remote data
15 collection site along with information identifying the patient and/or the medical professional who monitors the patient. This permits medical professionals the ability to review their patients' disease management state at intervals other than during regular appointments by e.g. logging into the data collection site via the bulletin board or internet connection. This provides many advantages to patients by permitting them to
20 have a storage location which can be used to monitor the long-term control of their disease.

The remote or local data storage system collects the information which is transferred from the monitoring instrument 1 and synchronizes and compiles it to eliminate duplicates from frequent uploads and interleaving of monitoring results if the
25 patient is using more than one monitoring instrument 1 as is contemplated. The time and data recording associated with each result may be used to accomplish this function. The data storage system associated with the invention can be developed from either relational or table driven database technologies, including software using Oracle™, Informix™, and Microsoft Access™ engines. The system can also work with a discrete

file system using a data management sub-system to effectively handle the numerous files.

A typical layout of the associated data to be stored in the data storage module of the invention includes time, date, monitoring reading, calories eaten, insulin dosage,
5 and time after exercise. However, many different pieces of information could be captured by a monitoring instrument 1 and transferred to the data storage system at the remote location 50 by operation of the system of the invention. The invention is intended to permit the patient to capture his or her disease state condition and store it for review and therapy modification.

10 One advantage of the invention is the simplification of the data capture method and the presence of a data collection system which is accessible by all patients to capture their data and permit it to be reviewed by their specific health care professional. An additional benefit is the simplification of the disease management by elimination of the need for noncomputer-trained patients to manually record all their data. Another
15 benefit of the system is the reduction in size and the convenience provided by elimination of the data communication functions and elimination or reduction in size of the user interface required to scroll through data stored in the monitoring instrument 1, set time and date, and communicate with current data management systems. Another advantage is that the communication module 11 can be used to recharge the batteries in
20 the monitoring 1 system to reduce the size of the device by minimizing the battery size.

In accordance with the invention, the monitoring instrument is designed or selected to work with the communication module 11. However, the communication module 11 can alternately be designed to work with a number of monitoring instruments for increased versatility. Similarly, it is possible to eliminate the
25 microprocessor 13 of communication module 11, along with random access memory 18 and use microprocessor 3 and memory module 4 of monitoring instrument 1. Additionally, the memory module 4 of the monitoring instrument can be designed to be removable such that it can interface, as a stand alone unit, with the communication module 11 to effect the information data exchange.

- An advantage of the invention is the simplification of the data capture method and the presence of a data collection system which is accessible by all patients to capture their data and permits it to be reviewed by their specific health care professional. An additional benefit is the simplification of the disease management by
- 5 elimination of the need for noncomputer-trained patients to manually record all their data. Another benefit of the system is the reduction in size and the convenience provided by elimination of the data communication functions and elimination or reduction in size of the user interface means required to scroll through data stored in the meter, set time and date, and communicate with current data management systems.
- 10 Another advantage is that the communication module can be used to recharge the batteries in the monitoring system to reduce the size of the device by minimizing the battery size. The invention is intended to permit patients to capture their disease state condition and store them at local or remote locations for review and therapy modification.
- 15 The above are exemplary modes of carrying out the invention and are not intended to be limiting. It will be apparent to those skilled in the art that modifications thereto can be made without departure from the spirit and scope of the invention as set forth by the following claims.

Claims:

1. A device for collecting and communicating analyte concentration information comprising:

5 a monitoring instrument adapted to operate in a collection mode and an interface mode in accordance with predetermined parameters, the monitoring instrument receiving the analyte concentration information and generating and storing information data representative of the analyte concentration information in the collection mode; and

10 a communication module adapted to operate in the interface mode and a transmission mode, the communication module interfacing with the monitoring instrument to download the information data from the communication module in the interface mode, the communication module selectively transmitting the information data to one or more locations remote from the communication module in the transmission
15 mode, the communication module comprising:

a communication port for effecting the interfacing of the communication module with the monitoring instrument;

20 a communication means for effecting the transmission to the one or more remote locations; and

an input means capable of inputting at least a portion of the predetermined parameters to the communication module.

25

2. The device of Claim 1, wherein the analyte concentration information is representative of the concentration of at least one blood analyte.

30

3. The device of Claim 1, wherein the analyte concentration information is representative of blood glucose concentration.

4. The device of Claim 1, wherein the analyte concentration information is representative of the concentration of at least one urine analyte.

5. The device of Claim 1, wherein the analyte concentration information is representative of the concentration of at least one interstitial fluid analyte.

6. The device of Claim 1, wherein the remote location is an internet site accessed through the modem.

7. The device of Claim 1, wherein the information data includes representations of one or more of monitoring readings, time and date stamps, meal times, exercise times, and therapy amounts.

8. The device of Claim 1, wherein the monitoring instrument operates as a stand alone unit independent of the communication module in the collection mode and is adapted to effect multiple collection mode operations prior to operation in the interface mode.

9. The device of Claim 1, wherein the monitoring instrument further comprises a rechargeable battery for powering the monitoring instrument, and wherein the communication module further comprises a battery recharger for charging the rechargeable battery in the interface mode.

10. The device of Claim 1, wherein the communication port is a first engaging portion disposed in the communication module and adapted to mate with a second engaging portion disposed on the monitoring instrument.

11. The device of Claim 10, wherein the mating activates the interface mode.

12. The device of Claim 10, wherein the mating activates the transmission mode.

5

13. The device of Claim 1, wherein the communication means encodes the data using morse code.

14. The device of Claim 1, wherein the communication means encodes the data using DTMF.

10

15. The device of Claim 1, wherein the communication means encodes the data using a Baudot format.

15

16. The device of Claim 1, wherein the communication means encodes the data using ASCII format.

17. The device of Claim 1, wherein the communication means encodes the data using Binary coded Decimal format.

20

18. A communication device for manipulating information data representative of analyte concentration information, the communication device comprising:

25

means for generating the analyte concentration information;

means for converting the analyte concentration information into digital form;

and

means for transmitting the converted analyte concentration information to a remote location.

19. The device of Claim 18, wherein the means for converting encodes the analyte concentration information using a set of no more than ten characters.

20. The device of Claim 18, wherein the means for converting encodes the analyte concentration information using a set of no more than eight characters.

21. A method for collecting and communicating analyte concentration information comprising:

gathering, in a collection mode, the analyte concentration information in a monitoring instrument;

generating, in the collection mode, information data representative of the analyte concentration information;

downloading, in an interfacing mode, the information data from the monitoring instrument to a communication module; and

selectively sending the information data, in a transmission mode, from the communication module to at least one remote location.

22. The method of Claim 21, wherein the analyte concentration information is representative of blood glucose concentration.

23. The method of Claim 21, wherein at least one of the collection, interfacing and transmission modes is governed by predetermined parameters communicated to the communication module from the remote location.

24. The method of Claim 21, further comprising the step of storing the information data in an electronic bulletin board at said remote location.

25. The method of Claim 21, further comprising the step of storing the
5 information data at an internet site at said remote location.

26. The method of Claim 21, wherein the information data includes one or more of monitoring readings, time and date stamps, meal times, exercise times, and therapy amounts.
10

27. The method of Claim 21, wherein at least one of the collection, interfacing and transmission modes is governed by predetermined parameters communicated to the communication means, the predetermined parameters comprising date and time entries, and wherein the remote processing system is adapted to
15 synchronize and interleaf the information data according to the date and time entries.

28. The method of Claim 23, wherein at least one of the collection, interfacing and transmission modes is governed by predetermined parameters communicated to the communication means, the predetermined parameters comprising
20 date and time entries, and wherein the information data is synchronized and interleaved at the electronic bulletin board according to the date and time entries.

29. The method of Claim 24, wherein at least one of the collection, interfacing and transmission modes is governed by predetermined parameters
25 communicated to the communication means, the predetermined parameters comprising date and time entries, and wherein the information data is synchronized and interleaved at the internet site according to the date and time entries.

30. The method of Claim 21, further comprising the step of sending the
30 information data in digital form.

31. The method of Claim 21, further comprising the step of encoding the information data using a set of no more than ten characters.

32. The method of Claim 21, further comprising the step of encoding the
5 information data using a set of no more than eight characters.

33. A method for manipulating information data representative of analyte concentration information, the method comprising the steps of:

10 generating the analyte concentration information;

converting the analyte concentration information into digital form; and

transmitting the converted analyte concentration information to a remote
15 location.

34. The method of Claim 32, wherein the step of converting comprises encoding the analyte concentration information using DTMF.

20 35. The method of Claim 32, wherein the step of converting comprises encoding the analyte concentration information using a Baudot format.

36. The method of Claim 32, wherein the step of converting comprises encoding the analyte concentration information using ASCII format.
25

37. The device of Claim 32, wherein the means for converting encodes the analyte concentration information using Binary coded Decimal format.

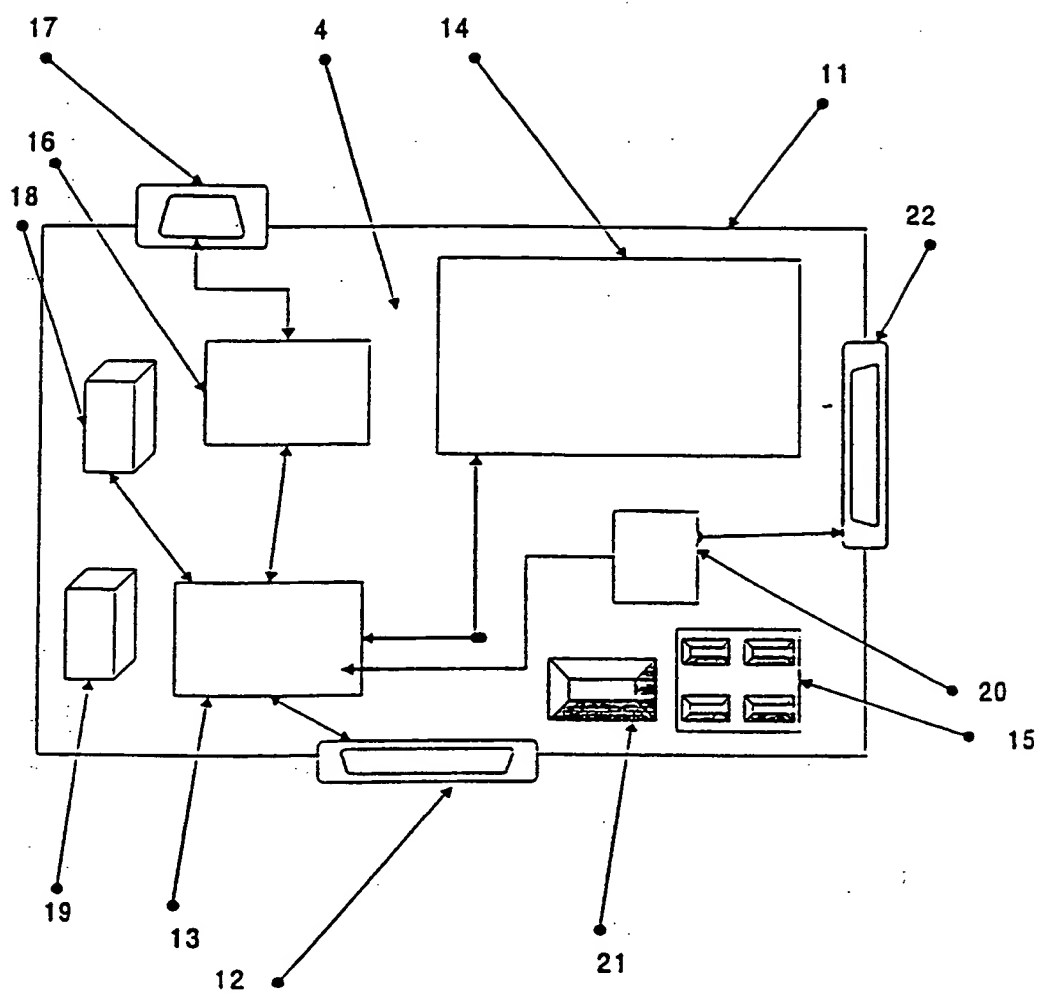


Figure 1

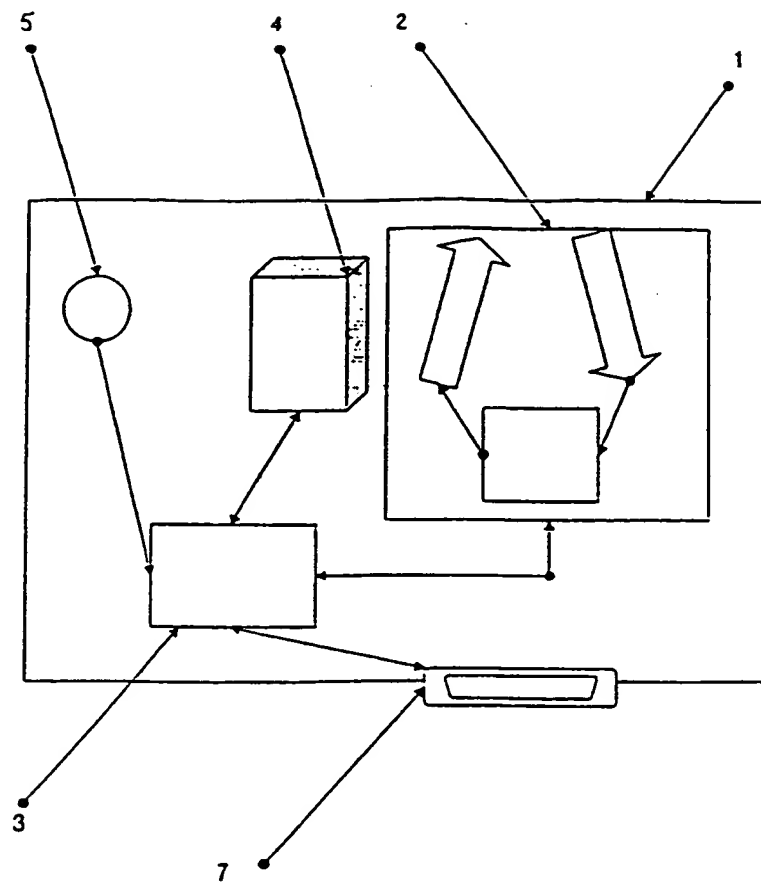


Figure 2

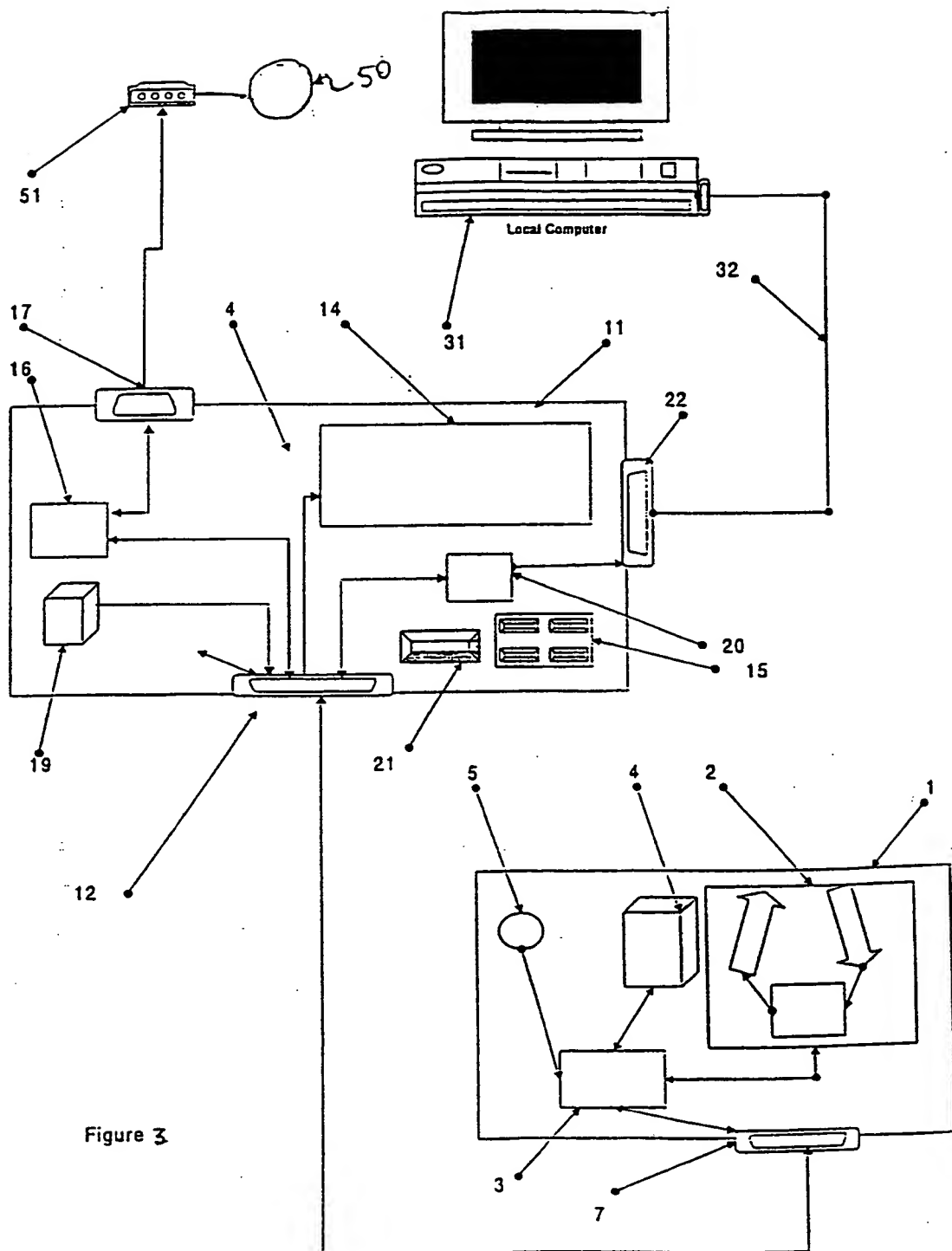


Figure 3

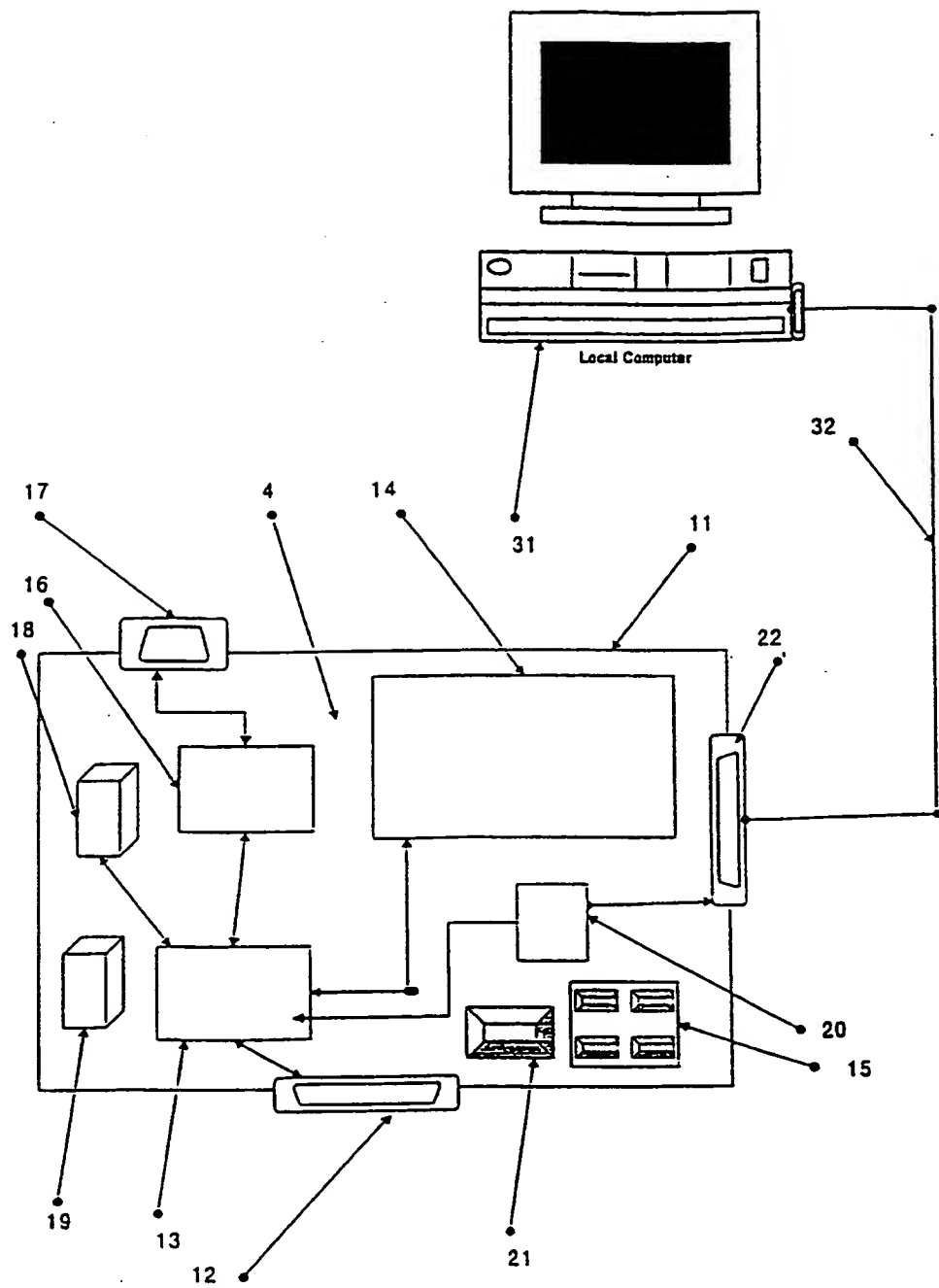


Figure 4

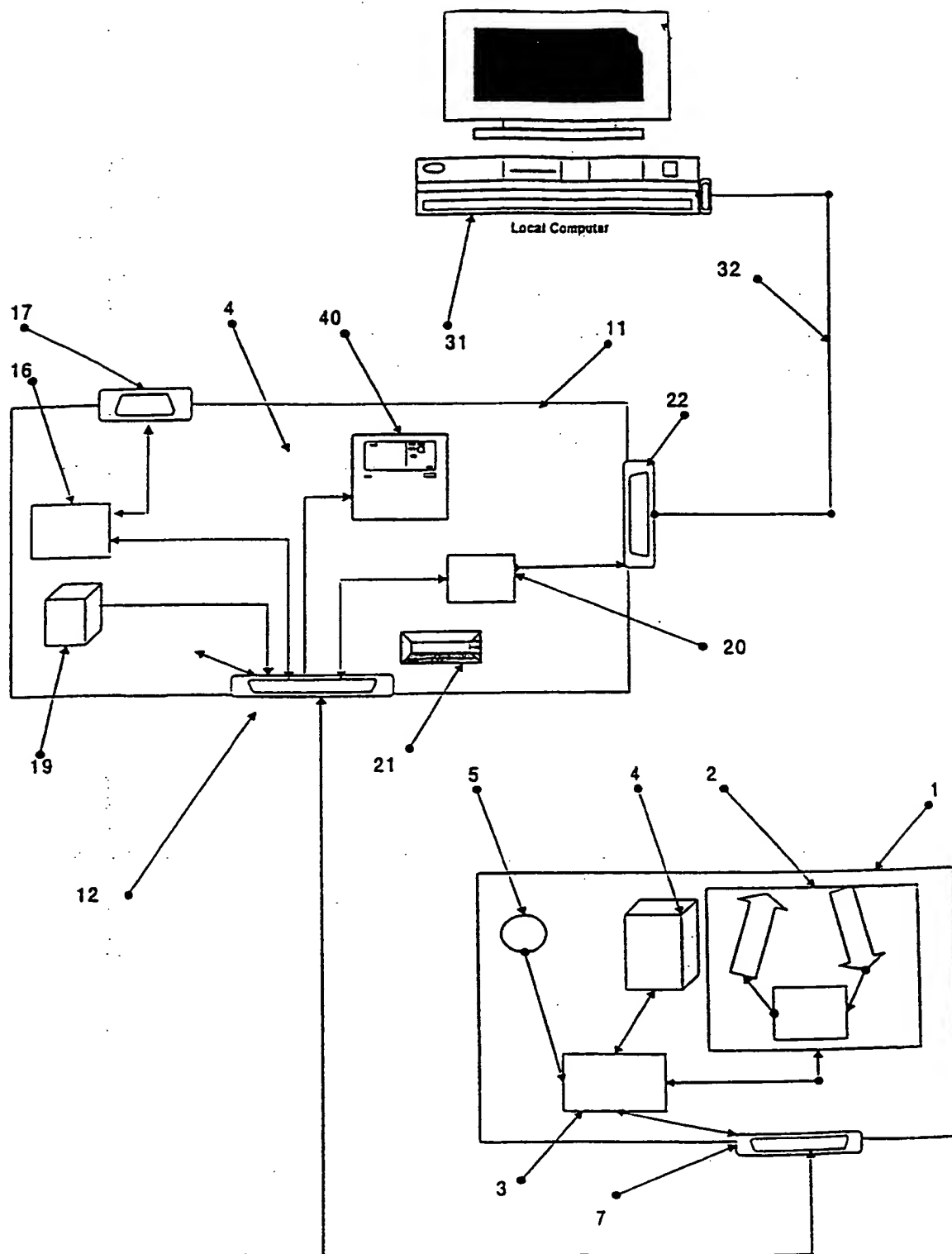


Figure 5

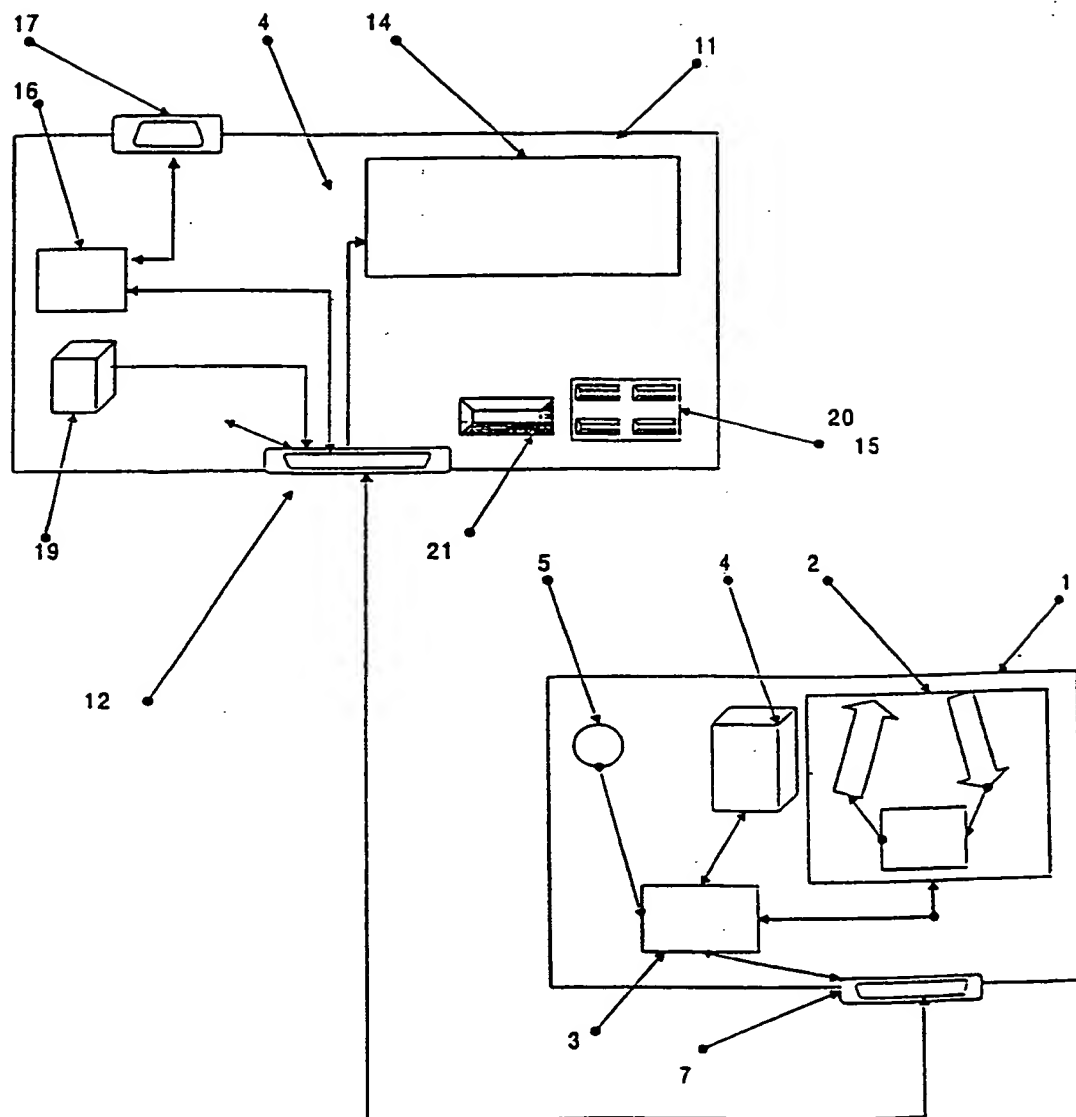


Figure 6

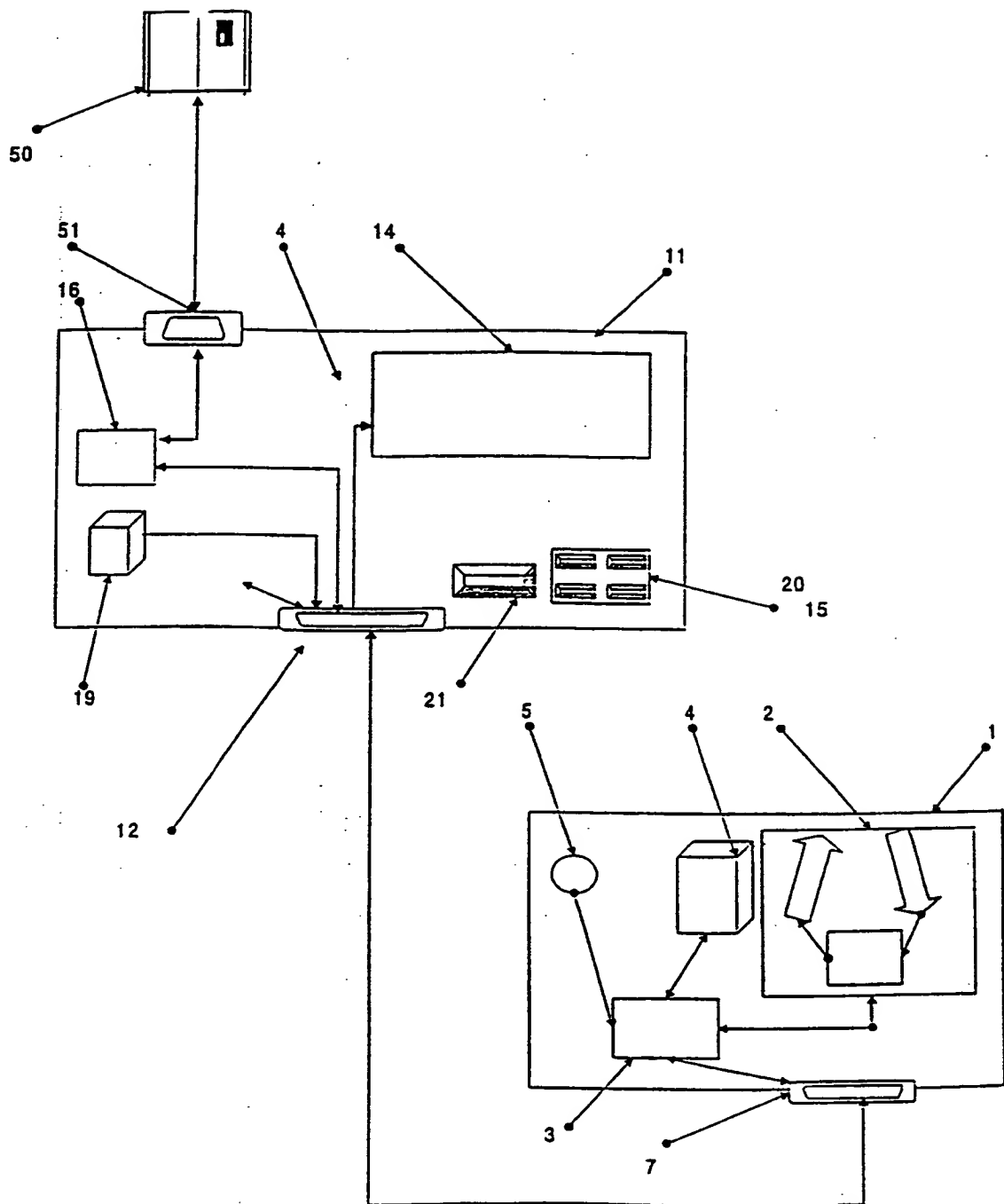


Figure 7

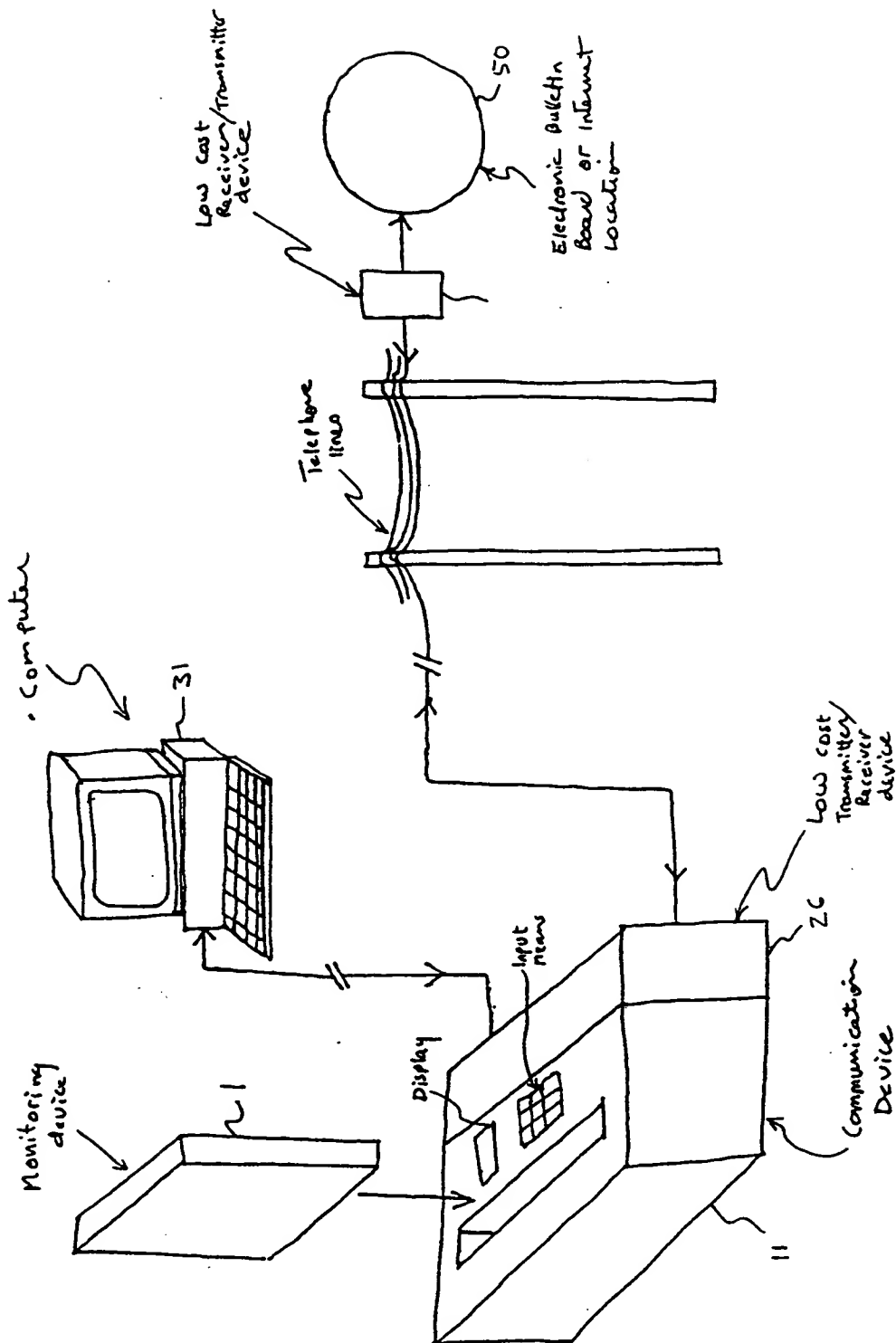


FIG. 8

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